



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

PASTAN et al.

Application No.: 09/684,599

Filed: October 5, 2000

For: MESOTHELIN, A
DIFFERENTIATION ANTIGEN
PRESENT ON MESOTHELIUM,
MESOTHELIOMAS AND OVARIAN
CANCERS AND METHODS AND KITS
FOR TARGETING THE ANTIGEN

Customer No.: 45115

Confirmation No. 2466

Examiner: Ungar, Susan

Technology Center/Art Unit: 1642

DECLARATION OF DR. IRA H. PASTAN

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

I, DR. IRA H. PASTAN, hereby declare and state:

1. I am the Ira H. Pastan named as an inventor of the above-captioned patent application. I received a Bachelor of Science degree, *magna cum laude*, from Tufts University, Medford, Massachusetts, in 1953 and the degree of Medical Doctor, *magna cum laude*, from Tufts Medical School in 1957. I performed an internship at Grace-New Haven Hospital, Yale University School of Medicine, New Haven, Connecticut, from 1957-58, and was a medical researcher at the Yale University School of Medicine from 1958 to 1959.

2. From 1959 to 1961, I was a clinical associate in the National Institute of Arthritis and Musculoskeletal Disease (NIAMD), of the U.S. National Institutes of Health (NIH), Bethesda, Maryland. From 1961 to 1962, I was a Postdoctoral Fellow in the Laboratory of Cellular Physiology, at the National Heart and Lung Institute of the NIH. From 1963-1969, I was a Senior Investigator in the Section on Endocrine Biochemistry, NIAMD, NIH. From 1969 to

1970, I was Head of the Molecular Biology Section, Endocrinology Branch, National Cancer Institute, NIH.

3. Since 1970, I have been Chief of the Laboratory of Molecular Biology ("LMB"), of the National Cancer Institute, NIH. The LMB currently has a staff of some 97 individuals, including 8 post-doctoral fellow, 5 pre-doctoral fellow, 15 visiting fellows, who are primarily scientists from other countries, senior Ph.D. or M.D. investigators who head the 10 sections into which the LMB is organized, and a number of research fellows, clinical fellows, nurses, and scientists of various levels assigned to the individual sections. Over the years, I have mentored and trained hundreds of scientists in techniques in immunology and cell biology, particularly in the identification of cancer antigens, in the generation of antibodies which bind to those antigens, identify against them, and in the development of immunotoxins using those antibodies to kill cells bearing the cancer antigens. A copy of my curriculum vitae is attached as Attachment 1.

4. I am an author or co-author of well over 1000 publications in the scientific literature. The full bibliography of my publications runs approximately 100 pages. Attachment 2 lists my publications during the years 1997 to 1999, the period around the priority date of the captioned application, showing my publications on discovering and characterizing cancer antigens and immunotoxins at that time, and during the period 2003 to 2004, to show that this work has continued since the filing of the application.

5. By virtue of my years of research and experience in discovering and characterizing cancer antigens, in developing and characterizing antibody-based therapeutics against cancer antigens, and in developing immunotoxins to kill cells expressing cancer antigens, I am knowledgeable about these areas. By virtue of my years as an editor of leading journals in the field and in training scores of scientists both from the United States and around the world, I am also knowledgeable about what persons of skill would understand from the present disclosure.

6. I understand that the Office Action dated June 3, 2005 in this proceeding contends that Chang et al., Cancer Research 52:181-186 (1992) ("Chang"), a paper on which I am a co-author, anticipates the present invention because it shows the mesothelin protein to be isolated on a

Western blot. I also understand that the Action states that the specification does not define which constitutes what constitutes substantially or essentially free of components which accompany a material in its native state and contends that "one of ordinary skill would immediately understand that the protein isolated in a western blot is substantially and essentially free of components which normally accompany it as found in its native state given that the claimed protein is substantially or essentially free of nucleic acid molecules which normally accompany it in its native state."

7. I disagree with the Action's contention because Chang does not show that we obtained isolated mesothelin. A western blot shows the presence on the blot of the protein targeted by the probe, despite the presence of any number of other proteins but it does not show the presence of any number of other proteins or cellular components that may or may not be present at the same time. We did not have an isolated protein when the Chang paper was published. In fact, it took the work reported in the present application before we were able to obtain and clone the protein now called mesothelin.

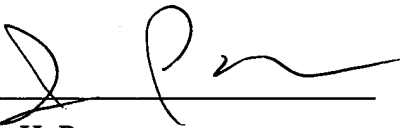
8. Based on my years as an editor and reviewer of the literature, and based on my four decades of experience in training of hundreds of persons of skill in the field, I further disagree with the Action's contention that one of ordinary skill would consider the terms "substantially" or "essentially free" to refer to a protein on a western blot, such as the one shown in Chang. With regard to a protein, I believe these terms would be understood by persons of ordinary skill in the art to refer to proteins that are sufficiently isolated to be sequenced and cloned. In my judgment, persons of skill would not consider a protein in a western blot, which has been electrophoresed but not separated from any other proteins which may be present with similar migration characteristics, to be substantially or essentially free of other cellular components. I would not find such a statement to be permissible in a journal article I was editing or by a pre- or post-doctoral fellow in my laboratory.

9. I understand the Action contends that the application does not teach residues which, it argues, are critical for the three dimensional structure of mesothelin. It is a commonplace in the art that the amino acid sequence of a protein determines its structure. Once a protein is

expressed, epitopes on the protein can be mapped, and these epitope maps identify the immunodominant portions of the protein. Individual peptides that raise antibodies can then be generated based on the portions of the molecule that are immunodominant. While this work may be time consuming, the amount of effort is considered in the art to be routine.

I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under § 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

12/1/05
Date


Dr. Ira H. Pastan

CURRICULUM VITAE

Name: Ira Harry Pastan

Date and Place of Birth: June 1, 1931; Winthrop, Massachusetts

Citizenship: United States of America

Marital Status: Married; three children

Education:

1953 B.S. -- Magna cum laude, Tufts University, Medford, Massachusetts

1957 M.D. -- Magna cum laude, Tufts Medical School

Brief Chronology of Employment:

- 1957-1958 -- Intern, Grace-New Haven Hospital, Yale University School of Medicine, New Haven, Connecticut
- 1958-1959 -- Assistant Research Medicine, Grace-New Haven Hospital, Yale University School of Medicine
- 1959-1961 -- Clinical Associate, National Institute of Arthritis and Musculoskeletal Disease (NIAMD), National Institutes of Health (NIH), Bethesda, Maryland
- 1961-1962 -- Postdoctoral Fellow, Laboratory of Cellular Physiology, National Heart and Lung Institute, NIH
- 1963-1969 -- Senior Investigator, Section on Endocrine Biochemistry, NIAMD, NIH
- 1969-1970 -- Head, Molecular Biology Section, Endocrinology Branch, National Cancer Institute (NCI), NIH
- 1970-Date -- Chief, Laboratory of Molecular Biology, CCR, NCI, NIH

Military Service:

Commissioned Officer, Public Health Service Reserve

7/01/59 – 6/30/61 -- Active status/Full grade

7/01/61 – 7/07/74 -- Inactive status

7/08/74 – 1997 -- Active status/Director grade

Licensure:

District of Columbia

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Societies:

Alpha Omega Alpha
 American Academy of Arts and Sciences
 American Association of Physicians
 American Association for the Advancement of Science
 American Society for Cell Biology
 American Society for Clinical Investigation
 American Society for Microbiology
 American Society of Biological Chemists
 Clinical Immunology Society
 Molecular Medicine Society
 National Academy of Sciences
 Peripatetic Club

Editorial Boards:

Endocrinology, 1967-1970
Journal of Biological Chemistry, 1970-1975; 1978-1983
Cell, 1973-1980
Journal of Cell Biology, 1975-1977
Biochemistry International, Associate Editor, 1980-1987
 Editor, *Experimental Cell Research*, 1980-1988
Journal of Cellular Physiology, 1981-1990
Molecular and Cellular Biology, 1986-1989
Journal of Cancer Communication, 1988
FASEB Journal, 1989
Proceedings of the Association of American Physicians
Molecular Medicine, Contributing Editor
Apoptosis, Editor
Tumor Targeting
Advances in Cyclic Nucleotide Research, Advisory Board
Biochimica et Biophysica Acta Reviews of Cancer, Advisory Editor
Molecular Cancer Therapeutics, 2001

Scientific Advisory Boards:

Dupont-Merck
 Stazione Zoologica di Napoli, Naples, Italy, 1992-1998
 Immunomedics, 1992-1995
 Duke External Scientific Advisory Board, Duke Comprehensive Cancer Center,
 Durham, North Carolina, 1997-2002

Chair, International Scientific Review Board, San Raffaele Scientific Institute, Milan, Italy, 1999-2001
 Università Degli Studi Di Napoli Federico II, Napoli, Italy, 1999-2000
 Micromet, Munich, Germany, 2002

Honors and Awards:

AOA, Tufts Medical School, Medford, Massachusetts, 1957
 Roche Award presented by Tufts Medical School, 1957
 Van Meter Prize Paper Co-author, American Thyroid Association, 1961
 Van Meter Prize presented by the American Thyroid Association, 1971
 Boxer Lectureship, Rutgers Medical School, New Brunswick, New Jersey, 1972
 Superior Service Award presented by the Department of Health, Education, and Welfare, National Institutes of Health, 1973
 Elected into Membership, The National Academy of Sciences, 1982
 Meritorious Service Medal presented by the Public Health Service, 1983
 Distinguished Service Medal presented by the Public Health Service, 1985
 Judith Segal Memorial Lecturer in Cancer Research, Hebrew University, Jerusalem, 1981
 Pierce Immunotoxin Award, Duke University Medical Center, Durham, North Carolina, 1988
 Director's Award, National Institutes of Health, 1991
 Elected into Membership, The American Academy of Arts and Sciences, 1992
 Fellow, American Academy of Microbiology, 1992
 First Anfinsen Memorial Lecturer, Weizman Institute, Israel, 1993
 Elected into Membership, The New York Academy of Sciences, 1993
 Special Achievement Award, presented by Coulter Corporation at the Nature Biotechnology Winter Symposium, Ft. Lauderdale, Florida, 1997
 Stanley Gore Memorial Lecturer, 12th International Conference on Brain Tumour Research and Therapy, Oxford, United Kingdom, 1997
 Fellow, American Association for the Advancement of Science, 1999
 R. E. "Bob" Smith Lecturer, MD Anderson Cancer Center, The University of Texas, Houston, Texas, 1999
 Charles Harkin Award for Research in Thyroid Cancer, National Cancer Institute, National Institutes of Health, Bethesda, Maryland, 1999.
 2000 Technology Transfer Award presented by the National Cancer Institute, National Institutes of Health, Bethesda, Maryland, 2000
 2001 A scientific symposium in honor of Ira Pastan entitled "Immunotherapy of Cancer: From the Laboratory to the Clinic" at the National Institutes of Health, Bethesda, Maryland, October 29, 2001.

Other Special Scientific Recognition (Partial List):

G. Burroughs Mider Lectureship, National Institutes of Health, 1973
 Burroughs Wellcome Visiting Professorship, 1978-1979
 Scientific Council, International Institute of Cellular and Molecular Pathology, Brussels, 1979-present

Windsor C. Cutting Lectureship, Stanford University, Stanford, California, 1980
 Special Visiting Professor, Stanford Medical Sciences Training Program, Stanford University, Stanford, California, 1980
 Chairman, Gordon Conference, "Cell Adhesion, Recognition and Movement," 1981
 Organizer, US-Japan Cooperative Cancer Research Program in Cell Biology
 Stanley Wright Memorial Lectureship, Western Society for Pediatric Research, 1982
 Home Office Reference Laboratory Lectureship, University of Kansas Medical Center, Lawrence, Kansas, 1982
 Fogarty International Center Committee, National Institutes of Health
 Counselor for American Society of Cell Biology
 President's National Advisory Council for Research, Howard University, Washington, D.C.
 Rennebohm Lecturer, University of Wisconsin School of Pharmacy, Madison, Wisconsin, 1988
 Member of Awards Committee of the American Society for Biochemistry and Molecular Biology
 Participant in the President's Cancer Panel on prostate cancer, 1992
 Organizer, US/Japan Cancer Seminar, 1993
 Committee Member, CENTRO, Naples, Italy, 1999

Invited Speaker (Partial List for Last Seven Years):

- 1998 15th International Conference "Advanced Application of Monoclonal Antibodies in Clinical Oncology," Santorini, Greece
 Experimental Therapeutics for Human Cancer, Frederick, Maryland
 2nd International Conference on Cancer Immunotherapy and Gene Therapy
 89th Annual American Association for Cancer Research
 Mini-Symposium Organizer for NIH Research Festival, Bethesda, Maryland
 "Biologic Principles for the Therapy of Human Colon Cancer," University of Texas, MD Anderson Cancer Center, Houston, Texas
 Mount Sinai Medical Center, Chemotherapy Foundation Symposium, Miami, Florida
 IBC Annual International Conference on Antibody Engineering, San Diego, California
- 1999 Seminars in Clinical and Molecular Oncology, NCI, DCS, NIH, Bethesda, Maryland
 Tufts University Graduate Student Seminar, Medford, Massachusetts
 Ninth International Conference on Human Retrovirology – HTLV, Japan
 Associazione Partenopea Ricerche Oncologiche, Fourth Molecular Oncology Meeting, Italy
 The 14th Annual Apffel Memorial Lecturer, Boston Cancer Research Association, Boston, Massachusetts
 Biological Therapy of Cancer from Basic Research to Clinical Application, Therapeutics Development Group of the EOTC, Munich, Germany
 Molecular Targets and Cancer Therapeutics: Discovery, Development and Clinical Validation, AACR and EORTC International Conference,

- Washington, D.C.
IBC Annual International Conference on Antibody Engineering, San Diego, California
- 2000 Symposium on Frontiers in Biomedical Research, University of Pennsylvania, Philadelphia, Pennsylvania
International Conference on Advances in Cancer Immunotherapy, New Jersey State Commission on Cancer Research and the Garden State Cancer Center, Princeton, New Jersey
Pittsburgh Cancer Institute Research Seminar Series, Pennsylvania
International Symposium on Tumor Targeted Delivery Systems, The Controlled Release Society and the National Cancer Institute, NIH, Bethesda, Maryland
Gab 2000 "International Symposium on Downstream Processing of Genetically Engineered Antibodies and Related Molecules," Barcelona, Spain
IBC Annual International Conference on Antibody Engineering, San Diego, California
- 2001 The 92nd Annual Meeting of the American Association for Cancer Research, New Orleans, Louisiana
First International Congress on Monoclonal Antibodies in Cancer, Banff, Canada
Yale Cancer Center, New Haven, Connecticut
XXVIII Meeting of the Italian Cancer Society, and the Università Degli Studi di Roma La Sapienza, Rome, Italy
Facolta di Medicina E. Chirurgia, University di Napoli "Federico II," Naples, Italy
- 2002 Sloan-Kettering Cancer Center, New York, New York
Swarthmore College, Swarthmore, Pennsylvania
Duke University Medical Center, Durham, North Carolina
Private Diagnostic Clinic, PLLC, Durham, North Carolina
IBC Antibody Engineering Conference, San Diego, California
General Motor Symposium, NIH, Bethesda, Maryland
Genentech, Inc., San Francisco, California
Cancer Intervention 2002, Grand Rapids, Michigan
Emory University, Atlanta, Georgia
9th Conference on Cancer Therapy with Antibodies Immunoconjugate, Princeton, New Jersey
9th Annual Cap CURE Scientific Retreat, Washington, DC
Case Western University, Cleveland, OH
- 2003 NCI Annual Symposium, NIH, Bethesda, Maryland
Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins, Baltimore, Maryland
NIH Undergraduate Scholarship Program's, NIH, Bethesda, Maryland
Department of Biochemistry and Biophysics, National Heart, Lung, and

Blood Institute, NIH, Bethesda, Maryland
IBC 14th Annual International Antibody Engineering Conference,
San Diego, CA

2004 IMSUT International COE Symposium, University of Tokyo, Japan
Hematology and Medical Oncology Grand Rounds, Memorial Sloan-Kettering
Cancer Center, New York, NY
Cambridge Healthtech Institute's Sixth Annual Phage and Molecular Display
Technologies: Targeting Disease Mechanisms Conference, Cambridge,
MA

SELECTED BIBLIOGRAPHY OF DR. IRA H. PASTAN

Publications during 1997-1998

861. Pai, L. and Pastan, I.: Immunotoxin therapy. In DeVita, V.T., Hellman, S., and Rosenberg, S.A. (Eds.): *Cancer: Principles and Practice of Oncology*, 5th Ed. Philadelphia, PA, Lippincott-Raven Press, 1997, pp. 3045-3057.
862. Kreitman, R.J. and Pastan, I.: Immunotoxins for treating cancer and autoimmune disease. In Harris, W. and Adair, J. (Eds.): *Antibody Therapeutics*. Boca Raton, FL, CRC Press, 1997, pp.33-51.
863. Benhar, I. and Pastan, I.: Tumor targeting by antibody-drug conjugates. In Harris, W. and Adair, J. (Eds.): *Antibody Therapeutics*. Boca Raton, FL, CRC Press, 1997, pp. 73-85.
864. Wellman, A., Krenacs, L., Fest, T., Scherf, U., Pastan, I., Raffeld, M., and Brinkmann, U.: Localization of the cell proliferation and apoptosis associated CAS protein in lymphoid neoplasms. *Am. J. Pathol.* 150: 25-30, 1997.
865. Sugimoto, Y., Sato, S., Tsukahara, S., Suzuki, M., Okochi, E., Gottesman, M.M., Pastan, I., and Tsuruo, T.: Co-expression of a multidrug resistance gene (MDR1) and herpes simplex virus thymidine kinase gene in a bicistronic vector Ha-MDR-IRES-TK allows selective killing of MDR1-transduced human tumors transplanted in mice. *Cancer Gene Ther.* 4: 51-58, 1997.
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867. Licht, T., Herrmann, F., Gottesman, M.M., and Pastan, I.: *In vivo* drug-selectable genes: A new concept in gene therapy. *Stem Cells* 15: 104-111 1997.
868. Husain, S.Y., Obiri, N.I., Gill, P., Zheng, T., Pastan, I., Debinski, W., and Puri, R.K.: Receptor for interleukin-13 on AIDS-associated Kaposi's sarcoma cells serves as a new target for a potent *Pseudomonas* exotoxin-based chimeric toxin protein. *Clin. Cancer Res.* 3: 151-156, 1997.
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871. Kobayashi, K., Pastan, I., and Nagatsu, T.: Controlled genetic ablation by immunotoxin-mediated cell targeting. In Houdebine, L.M. (Ed.): Transgenic Animals: Generation and Use. 1997, pp 331-336.
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878. Kreitman, R. and Pastan, I.: Recombinant toxins containing human granulocyte-macrophage colony-stimulating factor and either *Pseudomonas* exotoxin or diphtheria toxin kill gastrointestinal cancer and leukemia cells. Blood 90: 252-259, 1997.
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893. Lang, L., Jagoda, E., Wu, C.h., Brechbiel, M.W., Gansow, O.A., Pastan, I., Paik, Ch. H., Carrasquillo, J.A., and Eckelman, W.C.: Factors influencing the in vivo pharmacokinetics of peptides and antibody fragments: The pharmacokinetics of two PET-labeled low molecular weight proteins. *J. Nucl. Med.* 41: 55-61, 1997.
894. Wu, C., Kobayashi, H., Sun, B., Yoo, T.M., Paik, C.H., Gansow, O.A., Carrasquillo J.A., Pastan, I., and Brechbiel, M.W.: Stereochemical influence on the stability of radio-metal complexes in vivo. Synthesis and evaluation of the four stereoisomers of 2-(p-nitrobenzyl)-trans-CyDTPA. *Bioorg. Med. Chem.* 5: 1925-1934, 1997.
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901. Kreitman, R. and Pastan, I.: Accumulation of a recombinant immunotoxin in a tumor in vivo: Fewer than 1000 molecules per cell is sufficient for complete responses. *Cancer Res.* 58: 968-975, 1998.
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903. Lee, C.G.L., Gottesman, M.M., Cardarelli, C.O., Ramachandra, M., Jeang, K.-T., Ambudkar, S.V., Pastan, I., and Dey, S.: HIV-1 protease inhibitors are substrates for the MDR1 multidrug transporter. *Biochemistry* 37: 3594-3601, 1998.
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